

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
EASTERN DISTRICT

UNITED STATES OF AMERICA,)
)
Plaintiff,)
)
v.) No. 4:24-CR-00010-RLW-SPM
)
ASIM MUHAMMAD ALI, M.D., and)
MOHD AZFAR MALIK, M.D.,)
)
Defendants.)
)

**UNITED STATES OF AMERICA'S OPPOSITION TO MOHD AZFAR
MALIK, M.D.'S MOTION TO DISMISS THE DRUG TRAFFICKING COUNTS**

COMES NOW the United States of America, by and through its attorneys, Sayler A. Fleming, United States Attorney for the Eastern District of Missouri, and Amy E. Sestric, Assistant United States Attorney for said District, and opposes Mohd Azfar Malik, M.D.'s Motion to Dismiss the Drug Trafficking Counts ([ECF No. 54](#)):

INTRODUCTION

Federal law prohibits the unsupervised dispensation of controlled substances by anyone without a Drug Enforcement Administration (DEA) registration, regardless of whether that dispensation is for a legitimate medical purpose. [21 U.S.C. §§ 841\(a\)\(1\), 802\(a\)\(2, 10, 21\)](#). As the Indictment alleges, that is the precise crime that the defendants committed. Defendant Mohd Azfar Malik, M.D. (Malik) paid co-defendant Asim Muhammad Ali, M.D. (Ali) to run a ketamine clinic and use Malik's DEA registration to administer infusions of controlled substances to patients—all without Malik's supervision. As Malik well knew, during the entire time that Malik was paying Ali to administer ketamine and esketamine (brand name Spravato) to Malik's patients

without his supervision, Ali was under federal indictment and did not have a valid DEA registration.

Malik argues that by failing to allege that he “prescribed” ketamine for something other than a legitimate medical purpose, the Indictment has failed to allege the required elements of illegally “prescribing” controlled substances. But the Indictment does not charge a violation of the Controlled Substances Act (CSA), 21 U.S.C. § 801, et seq., based on the illegal *prescribing* of controlled substances, but rather, the *unsupervised administration* of controlled substances by someone who had no DEA registration, in violation of the express language of the CSA. Malik’s arguments are premised on a logical fallacy: that the only way in which a physician can illegally distribute a controlled substance is by prescribing it for no legitimate medical purpose. As discussed below, that is *one* way in which physicians can be liable under the CSA, but not the *only* way. The charged illegal act in this case is the unsupervised “administration”—which is the direct application of a controlled substance to the body of a patient—by an individual without a DEA registration.

Throughout his Motion to Dismiss the Drug Trafficking Counts (the Drug Trafficking Motion) (ECF No. 54), Malik attempts to minimize the conduct at issue, describing the violations as regulatory technicalities or suggesting (without support) that Ali merely “began assisting” him with ketamine infusions. (Drug Trafficking Mot., ECF No. 54, at 4, 9.) These descriptions are supported neither in law nor in fact, as Malik’s conduct—which was not simply receiving “assistance” from Ali—is squarely prohibited by the clear statutory language of the CSA.

To accept Malik’s arguments and dismiss this case is to adopt a theory that the CSA is a set of hyper-technical rules that can never be used to criminally prosecute a doctor for anything other than writing prescriptions without a legitimate medical purpose. But the law is clear that not

everything a doctor does is protected from liability under CSA, which makes all “transactions outside the legitimate distribution chain illegal.” *United States v. Moore*, 423 U.S. 77, 135 (1975) (citations omitted). One of those illegitimate transactions is the “lending out” of a practitioner’s DEA registration to another for purposes of running a clinic whose practice is centered on administering controlled substance infusions. That is exactly what the Indictment alleges, and the Drug Trafficking Motion should be denied.

PROCEDURAL HISTORY

On January 10, 2024, a federal grand jury indicted Malik and Ali in a 22-count Indictment. The Grand Jury charged Ali and Malik with: (1) one count of conspiracy to illegally distribute controlled substances and to maintain drug-involved premises in violation of 21 U.S.C. § 846; (2) one count of conspiracy to commit health care fraud in violation of 18 U.S.C. § 1349; (3) twelve counts of illegal distribution of a controlled substance in violation of 21 U.S.C. § 841(a)(1) and 18 U.S.C. § 2; (4) seven counts of making false statements related to health care matters in violation of 18 U.S.C. §§ 1035 and 2; and (5) one count of maintaining drug-involved premises in violation of 21 U.S.C. § 856(a)(2) and 18 U.S.C. § 2.

On February 28, 2024, Malik filed his Drug Trafficking Motion, which seeks dismissal of Counts One through 14 and Count 22 of the Indictment. Ali waived pretrial motions. (Notice of Intent and Response to Show Cause, ECF No. 62.)

FACTS¹

The Indictment alleges the following:

A. Background

Malik is a psychiatrist who, since at least as early as 1996, owned, operated, or served as the medical director for one or more health care businesses, including Psych Care Consultants, L.L.C. (PCC) and COPE Ketamine Clinic (COPE). (Indictment, ECF No. 2, ¶ 1.) PCC, a psychiatric clinic, had several locations, including its main location located in Suite 350 of the building located at 5000 Cedar Plaza Parkway in St. Louis, Missouri (the Cedar Plaza Building). (*Id.* ¶¶ 9-10, 37.) COPE was located in Suite 220 of the Cedar Plaza Building. (*Id.* ¶ 11.)

B. Controlled Substances

At all relevant times, Malik had two DEA registrations. (*Id.* ¶ 8.) A DEA registration is required by federal law for any person who dispenses controlled substances (*id.* ¶ 5), *i.e.* drugs that are classified by federal and state law into five different “schedules” depending on their potential for abuse and the severity of the effects if a person abuses the drug. (*Id.* ¶ 3.) As relevant here, ketamine and esketamine (an isomer of ketamine) are “schedule III” controlled substances; thus, they have less potential for abuse than drugs in schedules I² and II but more potential for abuse

¹ The Drug Trafficking Motion contains a section entitled “Statement of Relevant Facts.” (Drug Trafficking Mot., ECF No. 54, at 3.) That section sets forth a variety of facts not alleged in the Indictment, including irrelevant statements about Malik’s purported educational and career-related accomplishments, as well as a statement that “all of the ketamine and Spravato treatments prescribed by Dr. Malik were necessary to treat patients with treatment-resistant depression.” (*Id.* at 3-4.) For purposes of deciding a motion to dismiss, this inconsequential information must be disregarded. *United States v. Farm & Home Sav. Ass’n*, 932 F.2d 1256, 1259 (8th Cir. 1991) (“In reviewing the sufficiency of an indictment, we accept the government’s allegations as true, without reference to allegations outside the indicting document.”); *United States v. Long*, No. 4:20-CR-486-RLW-SPM, 2023 WL 2571560, at *1 (E.D. Mo. Mar. 20, 2023) (same).

² Drugs in schedule I are those that have “no currently accepted medical use in treatment in the United States.” 21 U.S.C. § 812(b)(1)(B).

than drugs in schedules IV and V. (*Id.* ¶ 4.) A provider must obtain a separate DEA registration for each location where he or she dispenses controlled substances. (*Id.* ¶ 7 (citing 21 U.S.C. § 822(e)(1); 21 C.F.R. § 1301.12)).

At no point relevant to this case did Ali have a DEA registration. As someone without a registration, Ali could not “administer” a controlled substance—that is, directly apply a controlled substance to the body of a patient—unless he was physically in the registered location and was being directly supervised by and in the physical presence of the practitioner under whose registration the controlled substance was being dispensed. (*Id.* ¶¶ 13-17 (citing 21 U.S.C. § 802(2); 21 C.F.R. § 1301.22(b); 19 C.S.R. §§ 30-1.066(1)(A), 30-1.011(1)(F))).

C. Drug Trafficking Conspiracy and Illegal Distribution of Controlled Substances

In or about late 2018, Malik created COPE, a clinic designed to provide ketamine infusions, which are intravenous ketamine administrations typically aimed at treating serious mental health illnesses, such as treatment-resistant depression, anxiety disorders, and post-traumatic stress disorders. (*Id.* ¶ 39.) At no time did Malik have a DEA registration to administer controlled substances from Suite 220 of the Cedar Plaza Building, *i.e.* the location of COPE. (*Id.* ¶ 40.)

Beginning in or about December 2020, Malik and Ali agreed that Ali, who knew he could not administer controlled substances given his lack of a DEA registration, would use Malik’s DEA registration to administer ketamine infusions to patients in Suite 220 of the Cedar Plaza Building without direct supervision by Malik and outside of Malik’s presence. (*Id.* ¶ 41.) Malik knew that Ali did not have a DEA registration, and therefore, could not lawfully dispense controlled substances, including ketamine, without Malik’s physical presence and supervision. (*Id.*)

Nonetheless, Malik and Ali determined that Malik could simply “say hi” to the ketamine patients, typically via telephone, as a purported justification for Ali handling their ketamine

treatment in the absence of Malik's physical presence or supervision while using Malik's DEA registration. (*Id.* ¶ 43.) In fact, following the commencement of the coronavirus disease (COVID-19) pandemic in early 2020, Malik rarely ever came into the Cedar Plaza Building, and was sometimes out of town while Ali was conducting ketamine infusions. (*Id.* ¶ 42.) Malik, through one or more of his businesses, paid Ali for each ketamine infusion that Ali administered to a patient. (*Id.* ¶ 44.)

The drug trafficking conspiracy was not limited to ketamine. Malik and Ali eventually agreed that Ali would administer not only ketamine infusions under Malik's DEA registration number, but also treatments of Spravato, a nasal spray containing the active ingredient esketamine, a controlled substance.³ (*Id.* ¶¶ 18, 46.) Like the ketamine infusions, the Spravato administrations were conducted by Ali in Suite 220 of the Cedar Plaza Building outside of Malik's presence and without supervision, even though (1) Ali knew he could not administer controlled substances without a DEA registration, and (2) Malik knew he was required to provide direct supervision and to be physically present for Spravato treatments, and (3) the COPE clinic location did not have the legally required DEA registration, and that, therefore, no controlled substances could be administered at that location. (*Id.* ¶ 46.)

D. Illegal Storage and Distribution of Controlled Substances

Malik and Ali agreed to illegally maintain drug-involved premises, in that they managed and controlled Suite 220 of the Cedar Plaza Building, and knowingly and intentionally made it available for the purpose of unlawfully storing and distributing ketamine and esketamine, as set forth above. (*Id.* ¶ 47.)

³ Due to the risks of sedation, dissociation, respiratory depression, and abuse and misuse, Spravato is subject to strict oversight by the Food and Drug Administration (FDA), in addition to the oversight effectuated by the CSA and its implementing regulations. (*Id.* ¶¶ 19-21.)

STANDARD

Federal Rule of Criminal Procedure 12(b)(3)(B)(v) provides that a motion to dismiss may be filed for failure to state a claim.⁴ To assess such a motion, the Court must accept the allegations stated in the Indictment as true and “ask whether they can form the basis of the charged offense.” *United States v. Hansmeier*, 988 F.3d 428, 436 (8th Cir. 2021). “An indictment adequately states an offense if: it contains all of the essential elements of the offense charged, fairly informs the defendant of the charges against which he must defend, and alleges sufficient information to allow a defendant to plead a conviction or acquittal as a bar to subsequent prosecution.” *United States v. Hayes*, 574 F.3d 460, 472 (8th Cir. 2009) (quoting *United States v. Sewell*, 513 F.3d 820, 821 (8th Cir. 2008)). Further, “[a]n indictment is normally sufficient if its language tracks the statutory language. *Sewell*, 513 F.3d at 821.

ARGUMENT

The crux of Malik’s Drug Trafficking Motion is that, according to him, the United States’ case must be dismissed unless the Government alleges that Malik “prescribed” controlled substances illegally—that is, by issuing prescriptions other than for a legitimate medical purpose. 21 C.F.R. § 1306.04. Malik contends the failure to so allege constitutes “egregious misuse” of the Government’s prosecutorial authority. (Drug Trafficking Mot., ECF No. 54, at 6.) Malik, however, misunderstands the law. Illegal prescribing is *one* way in which DEA-registered physicians may be held criminally liable under the CSA. However, it is not the *only* way in which

⁴ Malik purports to bring the Drug Trafficking Motion “pursuant to Federal Rule 12(b)(6) for failure to state a claim.” (Drug Trafficking Mot., ECF No. 54, at 1.) The United States assumes Malik errantly cited this civil rule and intends to bring his Motion pursuant to Federal Rule of Criminal Procedure 12(b)(3)(B)(v).

physicians may be held criminally liable under the CSA. And, moreover, it is not the way in which the Grand Jury found probable cause to believe that Malik committed crimes under the CSA.

More specifically, Malik overlooks that the Indictment accuses him not of illegally prescribing, but of conspiring to illegally *administer* controlled substances by allowing someone with no DEA registration to infuse ketamine directly into patients without his supervision and outside his presence, all under the “authority” of his DEA registration. These acts are plainly outside of the scope of authorized behavior defined by the CSA. As a result, and as further explained below, nothing in the CSA requires the Government to allege (or prove) that the ketamine and Spravato treatments Ali performed were for no legitimate medical purpose.

A. The Plain Language of the CSA Makes the Unsupervised Administration of Controlled Substances an Illegal, Unauthorized Act.

This case is premised on the illegal *administration* of controlled substances, and, contrary to Malik’s arguments, the conduct described in the Indictment is prohibited by the plain statutory language of the CSA itself. “Except as authorized,” the CSA prohibits any person from knowingly or intentionally dispensing controlled substances. 21 U.S.C. § 841(a)(1). DEA-registered “practitioners” may “dispense” controlled substances within the confines of the CSA. 21 U.S.C. § 823(g)(1). The term “dispense” means “to deliver a controlled substance to an ultimate user or research subject by, or pursuant to the lawful order of, a practitioner, including the prescribing and administering of a controlled substance” 21 U.S.C. § 802(10).

Critically, the term “administer” means “the direct application of a controlled substance to the body of a patient or research subject by . . . a practitioner (or, *in his presence*, by his authorized agent)” 21 U.S.C. § 802(2)(A) (emphasis added). The term “practitioner” includes a variety of different types of health care professionals, including physicians, so long as they are “licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which [they practice]

to distribute, dispense, conduct research with respect to, [or] administer . . . a controlled substance in the course of professional practice or research.” 21 U.S.C. § 802(21) (emphasis added). In short, the CSA expressly requires the DEA-registered practitioner to be present during the administering of a controlled substance.

The Indictment alleges that Malik was not present when Ali, who had no registration, infused ketamine into patients or administered Spravato to them under the purported “authority” of Malik’s DEA registration. (Indictment, ECF No. 2, ¶¶ 12, 42-43.) Accordingly, Malik’s contention that “[o]ur drug trafficking statutes simply do not encompass Dr. Malik’s conduct” (Drug Trafficking Mot., ECF No. 54, at 14) is simply wrong. Malik did not merely “[run] afoul of regulations (like storing medicine on the wrong floor of his medical office).” (*Id.* at 1.) He ran afoul of the CSA.

That Missouri has promulgated regulations consistent with the CSA’s mandates regarding the administration of controlled substances does not, as Malik would have it, convert criminal conduct into a hyper-technical violation of “medical regulations.” (Drug Trafficking Mot., ECF No. 54, at 5.) Missouri regulations, like the laws of many other states, do dictate that the administration of controlled substances must occur by the DEA registrant or under their direct supervision and in their physical presence. 19 C.S.R. §§ 30-1.066(1)(A), 30-1.011(1)(F). And the CSA promulgating regulations expressly adopt any state requirements regarding administration in addition to those imposed by the CSA. 21 C.F.R. § 1301.22(b). These provisions, however, merely underscore what is obvious from the CSA statutory provisions themselves: the legislative and administrative bodies responsible for these laws care deeply that dangerous controlled substances are administered only under proper supervision by a registered practitioner. The Court

should decline Malik’s invitation to treat these serious rules designed to protect public safety as mere technicalities.

B. The Existence of a Purported Legitimate Medical Purpose is Irrelevant to Whether Malik Illegally Administered Ketamine and Spravato.

The Government does not dispute that registered physicians who *write prescriptions* for controlled substances *must* do so for a legitimate medical purpose in the usual course of their professional practice. 21 C.F.R. § 1306.04; *see also Ruan v. United States*, 597 U.S. 450 (2022). But as set forth below, the requirement that registered practitioners prescribe controlled substances for a legitimate medical purpose is not a defense to the allegations in the Indictment that Malik conspired to allow a non-DEA registered individual to administer ketamine and Spravato without supervision and outside of his presence.

1. The “Legitimate Medical Purpose” Language Malik Relies Upon Originates from 21 C.F.R. § 1306.04—An Inapplicable Prescription Regulation.

Under 21 C.F.R. § 1306.04(a), “[a] prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.” Malik contends that 21 C.F.R. § 1306.04 serves as an “exception” under the CSA for doctors to prescribe “and distribute” controlled substances. (Drug Trafficking Mot., ECF No. 54, at 7.). Malik interprets § 1306.04 to apply to the administration, rather than the prescription, of controlled substances, an expansion of *Ruan* well beyond a scope any court has recognized for the application of § 1306.04.

Nothing in § 1306.04 creates a general “exception” allowing doctors to “distribute” controlled substances. In fact, the term “distribute”—which refers to the “deliver[y] (other than by administration or dispensing) [of] a controlled substance,” 21 U.S.C. § 802(11)—does not appear in § 1306.04 at all. Moreover, § 1306.04 is one of several sections of Part 1306 (entitled

“Prescriptions”) of the regulations promulgated under the CSA. Part 1306 specifically pertains to “the issuance, filling and filing of prescriptions . . .” 21 C.F.R. § 1306.01. Importantly, the definition of “prescription” expressly excludes “an order for medication which is dispensed for immediate administration to the ultimate user . . .”⁵ 21 C.F.R. §§ 1300.01, 1306.02.

In other words, by the very terms of the regulations, § 1306.04 is limited to prescriptions and does not apply to controlled substance administrations, such as ketamine infusions or Spravato treatments. As a result, Malik’s contention that § 1306.04 requires the Government to prove a lack of legitimate medical purpose in this case has no merit.

For the same reasons, the remaining authorities that Malik cites do not apply. Malik cites, for example, the Eighth Circuit Model Jury Instructions for the proposition that the Government must, in this case, allege that the ketamine and Spravato treatments performed by Ali had no legitimate medical purpose. (Drug Trafficking Mot., ECF No. 54, at 7.) What the Eighth Circuit Model Jury Instructions say, however, is that “[p]hysicians and others are authorized to dispense controlled substances *via prescription* if it is ‘issued for a legitimate medical purpose by an individual practitioner⁶ acting in the usual course of his professional practice.’” 8th Cir. Model Jury Instructions, § 6.21.841A (quoting 21 C.F.R. § 1306.04) (emphasis added).

Likewise, the cases that Malik relies on address circumstances not applicable here. In Malik’s cases, the relevant conduct pertained to prescribing, not to the administration of controlled substances by someone without a DEA registration. *See United States v. Smithers*, 92 F.4th 237,

⁵ The evidence at trial will show that the ketamine Ali infused without supervision was ordered from various third-party retailers and then stored in Suite 220 of the Cedar Plaza Building for immediate administration to patients in the COPE clinic. The ketamine that Ali infused was not “prescribed” or otherwise filled at pharmacies for patients to retrieve and subsequently bring into COPE for administration.

⁶ Again, a “practitioner” is someone who is authorized to dispense controlled substances. 21 U.S.C. § 802(21).

240 (4th Cir. 2024) (“Joel Smithers, until this prosecution a doctor of osteopathy, was convicted on 861 counts, all related to his opioid-prescribing practices.”); *United States v. Ly*, 543 Fed. Appx. 944, 946-47 (11th Cir. 2013) (affirming conviction under § 841(a)(1) in case where defendant, though rarely examining his patients, “prescribed” high doses of controlled substances that pharmacies sometimes refused to fill); *United States v. Smith*, 573 F.3d 639, 647 (8th Cir. 2009) (“Smith was convicted of conspiracy to distribute controlled substances and aiding and abetting the distribution of controlled substances without an effective prescription.”); *United States v. Feingold*, 454 F.3d 1001, 1003-05 (9th Cir. 2006) (describing the defendant’s problematic prescribing practices and further noting that the “CSA makes exceptions . . . for certain individuals who are *registered* ‘practitioners’ under the Act” (emphasis added)); *United States v. Katz*, 445 F.3d 1023, 1025 (8th Cir. 2006) (“Dr. Katz prescribed medications to patients upon request and was . . . eventually indicted based on prescriptions he wrote for fifteen people”); *United States v. Tran Trong Cuong*, 18 F.3d 1132, 1133 (4th Cir. 1994) (defendant, a DEA-registered physician, was indicted for “knowingly and willfully distributing and dispensing *by prescription* various quantities of Schedule II through V controlled substances” (emphasis added)); *United States v. Stump*, 735 F.2d 273, 274 (7th Cir. 1984) (“Eventually Doctor Stump was charged with thirty counts of illegally prescribing controlled substances.”); *United States v. Bartee*, 479 F.2d 484, 485-86 (10th Cir. 1973) (describing prescribing conduct for which defendant was charged).

None of Malik’s cited authorities address the circumstances here, where one coconspirator, Malik, violated the clear terms of the CSA by allowing his coconspirator, Ali—without any DEA registration whatsoever—to administer controlled substances directly to patients without supervision using the DEA registration of another person.

2. *Ruan v. United States* Did Not Repeal the CSA’s Statutory Proscription of Unauthorized Acts.

Malik contends that the 2022 Supreme Court decision *Ruan v. United States*, 597 U.S. 450 (2022), supports his position. Specifically, he states:

In *Ruan*, the Supreme Court made clear in a unanimous opinion that the Government must not only prove that a doctor was dispensing the controlled substances without a legitimate medical purpose and beyond the bounds of medical practice, but also that the doctor *subjectively* did so with bad intent.

Drug Trafficking Mot., ECF No. 54, at 8 (emphasis in original).) Malik reads *Ruan* both incorrectly and too broadly.

When it comes to what is and is not “authorized” under the CSA, the language of *Ruan* is not nearly as all-encompassing as Malik suggests. Instead, it is extremely precise and clearly limited to cases involving the prescribing (not administration) of controlled substances by registered practitioners. In the opinion’s first paragraph, the Court states, “*Registered doctors may prescribe [controlled] substances to their patients. But, as provided by regulation, a prescription is only authorized when a doctor issues it ‘for a legitimate medical purpose . . . acting in the usual course of his professional practice.’”* 597 U.S. at 454 (quoting 21 C.F.R. § 1306.04(a)) (emphasis added)). The Court expressly noted that both petitioners were doctors who “possessed licenses permitting them to prescribe controlled substances,” and it posed the question presented as:

To prove that a doctor’s dispensation of drugs via prescription falls within the [CSA’s] prohibition and outside the authorization exception, is it sufficient for the Government to prove that prescriptions was *in fact* not authorized, or must the Government prove that the doctor *knew* or *intended* that the prescription was unauthorized?

Id. at 454-55 (emphasis in original). The Court held that “[a]fter a defendant produces evidence that he or she was authorized to dispense controlled substances, the Government must prove

beyond a reasonable doubt that the defendant knew that he or she was acting in an unauthorized manner, or intended to do so.” *Id.* at 454.

Nothing in *Ruan*, which addressed a question of *mens rea*, changed what “authorized” means. What is “authorized” remains precisely defined by the CSA, which, in turn, makes clear that Malik was not “authorized” to allow Ali to administer controlled substances using his DEA registration and without his supervision or presence. As stated in *Ruan*, “a lack of authorization is often the critical thing distinguishing wrongful from proper conduct,” *id.* at 460, and it is so here. Because the conduct alleged in the Indictment was unauthorized by the CSA, Malik is not excepted in any manner from liability.⁷

3. Courts Have Expressly Rejected Defendants’ Attempts to Invoke a Legitimate Medical Purpose Defense Where the Defendant Exceeded the Scope of, or Acted Without, a Valid DEA Registration.

As set forth above, the authorities Malik cites are inapposite in that they relate to charges brought against DEA-registered practitioners who write prescriptions and thus are subject to the requirements of 21 C.F.R. § 1306.04. There are, however, cases more akin to the instant one in that they pertain to providers who either had no DEA registration or exceeded the scope of their registration. In such cases, courts have held that the defendants’ acts were not “authorized” by the CSA, and the inquiry ended there without any need to find a lack of legitimate medical purpose.

For example, in *United States v. Blanton*, the defendant was a physician who was convicted of illegally distributing methaqualone, a controlled substance, in violation of § 841(a)(1). 730 F.2d

⁷ For these reasons, and because *Ruan* was not fundamentally about what conduct is “authorized” under the CSA, Malik is off point when he cites cases (*see* Drug Trafficking Mot., ECF No. 54, at 10) that discuss the effect of *Ruan*’s *mens rea* holding on various convictions. *United States v. Hollington*, No. 3:22-CR-141-TJC-PDB, 2023 WL 4315747, at *4 (M.D. Fla. July 3, 2023) (“Hollington’s reliance on [Ruan] is unhelpful, as *Ruan* does not concern dismissal of an indictment but rather what the Government must prove at trial for a charge brought under 21 U.S.C. § 841. . . . Accordingly, Hollington’s motion is due to be denied.”).

1425, 1427 (11th Cir. 1984). Although the defendant had a DEA registration, the registration did not authorize the defendant to dispense the specific schedule of drugs in which methaqualone was classified. *Id.* at 1427-28. The defendant argued that “the trial judge improperly charged the jury that he could be convicted for simply not complying with the technicalities of the registration requirement.” *Id.* at 1429. Citing the Supreme Court’s decision in *United States v. Moore*, 423 U.S. 77 (1975), the defendant complained he was convicted “without proof that the drugs were dispensed outside the bounds of professional practice.” *Blanton*, 730 F.2d at 1429-30.

The Eleventh Circuit disagreed, finding the CSA only allowed “authorized” individuals to dispense controlled substances “to the extent authorized by their registration.” *Id.* at 1429 (quoting 21 U.C.S. § 822(b)). Rejecting the defendant’s reliance on *Moore*, the court explained that “*Moore* involved the question of whether a physician could ever be prosecuted under section 841(a)(1) for dispensing drugs *for which he was registered*.” *Id.* at 1430 (emphasis in original). The court elaborated, “*Moore* does not . . . support the argument that a physician not registered to dispense the drugs he is dispensing could not be prosecuted if his activity would be within the usual course of professional practice, if he had been registered.” *Id.* The defendant “clearly fell] within the statutory prohibition . . . because he was not registered to dispense methaqualone,” and thus his conviction was affirmed. *Id.*

Similarly, in *United States v. Jones*, a physician’s assistant who was convicted under § 841(a)(1) for prescribing controlled substances argued that his conviction should be overturned because the medications were “for valid medical reasons and were authorized by his supervising physician . . . ” 816 F.2d 1483, 1484-85 (10th Cir. 1987). The Tenth Circuit disagreed, finding he was not “authorized” under the CSA to prescribe controlled substances. *Id.* at 1485. The court explained that “[a]lthough some of his prescriptions may have been for valid medical reasons, [the]

defendant [was] not a physician, nor [was] he registered with the DEA.” *Id.* His convictions under § 841(a)(1) were affirmed. *Id.* at 1488.

Additionally, in *United States v. Cheek*, the Sixth Circuit found that a physician whose DEA registration had been revoked enjoyed no exception under the CSA for prescribing activities she conducted under the active registration of another doctor. 592 Fed. Appx. 179, 181-82 (6th Cir. 2014). Without a registration, the defendant did not qualify as a “practitioner” under the CSA and thus her activities were not “authorized.” *Id.* (citing 21 U.S.C. § 802(21) and *Blanton*, 730 F.2d at 1429-30); *see also Duval v. United States*, 372 F. Supp. 3d 544 (E.D. Mich. 2019) (rejecting defendant’s argument that, because he was registered as a “caregiver” under state law, he was authorized to sell marijuana, and further denying motion to vacate sentence under 28 U.S.C. § 2255 because there was no evidence that defendant ever held a DEA registration).

Like the defendants in *Blanton*, *Jones*, and *Cheek*, Malik’s actions were outside the scope of his DEA registration, which did not authorize him to administer controlled substances except by doing it himself or by being in the physical presence of someone he was directly supervising. 21 U.S.C. §§ 802(2), 841(a)(1); 21 C.F.R. § 1301.22(b); 19 C.S.R. §§ 30-1.066(1)(A), 1-1.011(1)(F). In other words, Ali did not have a DEA registration and Malik exceeded the bounds of his. These violations are not mere “technicalities of the registration requirement.” *Blanton*, 730 F.2d at 1429. As the *Blanton* court recognized, “[t]he ‘concept of ‘registration’’ is the heart of the [CSA].” *Id.* at 1430 (quoting *Moore*, 423 U.S. at 140). Malik asks this Court to allow unregistered physicians to dispense controlled substances under the DEA authority of other practitioners so long as there was a legitimate medical purpose. This interpretation defies the plain language, and meaning, of the Controlled Substances Act.

4. The Requirements for Valid Controlled Substance Prescriptions Do Not Serve as a Shield Against All of the Many Other Types of CSA Liability.

In 1975, the Supreme Court decided the seminal case *United States v. Moore*, holding that a DEA-registered physician can, in fact, be prosecuted under § 841 for prescribing outside the usual course of professional practice.⁸ 423 U.S. at 126-27. The Court explained that “the scheme of the statute, viewed against the background of the legislative history, reveals an intent to limit a registered physician’s dispensing authority to the course of his ‘professional practice.’” *Id.* at 140. The Court relied on Congress’s intent “to strengthen rather than to weaken” previously existing drug laws and found that although the CSA “authorizes transactions within the legitimate distribution chain,” it “makes all others illegal.” *Id.* at 139-41 (internal quotations omitted). The

⁸ Malik does not dispute that the Indictment sufficiently alleges that he acted outside the usual course of professional practice. Nor could he. The Indictment alleges that Malik illegally allowed Ali to use his DEA registration to run a ketamine clinic, without his supervision even though he knew Ali had no registration to deal in controlled substances. (Indictment, ECF No. 2, ¶ 41.) It further alleges that Malik and Ali agreed that Malik would “simply ‘say hi’ to the ketamine patients,” and that Malik was rarely even in the Cedar Plaza Building and sometimes even out of town while he allowed Ali to infuse ketamine under his DEA registration number. (*Id.* ¶¶ 42-43.) Additionally the Indictment alleges that Malik and Ali extended this conspiracy to Spravato treatments, which they then billed to Medicare under Malik’s name to “conceal that Dr. Ali was the actual rendering provider” (*Id.* ¶¶ 45-46, 54-55.) These circumstances, which describe an abdication of Malik’s role as a physician and comprise violations of state and federal laws, are more than enough to allow a jury to conclude that Malik acted outside of the usual course of professional practice. *See United States v. Sabeen*, 885 F.3d 27, 46-47 (1st Cir. 2018) (whether defendant acted outside the usual course of professional practice requires case-by-case review of the evidence, and “jurors may infer bad faith from conduct that is commonly understood to be plainly unprofessional”); *United States v. Volkman*, 797 F.3d 377, 386 (6th Cir. 2015) (reiterating long-standing endorsement of “a broad approach to determining what conduct falls outside the accepted bounds of professional practice so as to constitute a CSA violation, eschewing a preestablished list of prohibited acts in favor of a case-by-case approach”); *Cheek*, 592 Fed. Appx. at 182 (outside of the usual course of professional practice for a physician without a DEA registration to call in a prescription under another physician’s DEA registration); *United States v. Kanner*, 603 F.3d 530, 534 (8th Cir. 2010) (favorably citing authority “allow[ing] violations of state regulations of medical practice as relevant evidence of guilt under 21 U.S.C. § 841” (internal citations omitted)); *United States v. Vamos*, 797 F.2d 1146, 1151 (2d Cir. 1986) (“The term ‘professional practice’ refers to generally accepted medical practice; a practitioner is not free deliberately to disregard prevailing standards of treatment.”).

Supreme Court explicitly acknowledged that the CSA was intended to “confine authorized medical practice within accepted limits.” *Id.* at 141-42. As the Supreme Court has recognized, the criteria for valid prescriptions are just that: a set of requirements that DEA-registered practitioners must follow. They do not, as Malik insinuates throughout his Drug Trafficking Motion, serve as a safe haven that allows physicians to do whatever they please with controlled substances, especially if, as in this case, the conduct is squarely in violation of the CSA.

C. Malik’s Unsupported Version of the Facts Are Not a Basis to Dismiss the Indictment.

Finally, Malik argues that the Indictment should be dismissed because, he says, he in fact “prescribed ketamine and esketamine exclusively for legitimate medical purposes.” (Drug Trafficking Mot., ECF No. 54, at 11.) For all of the above reasons, even assuming this as true,⁹ it is no defense to the Indictment. Regardless, Malik’s attempt to obtain dismissal with unsupported facts that fall outside the Indictment should be rejected. *Farm & Home Sav. Ass’n*, 932 F.2d at 1259 (“In reviewing the sufficiency of an indictment, we accept the government’s allegations as true, without reference to allegations outside the indicting document.”); *Long*, 2023 WL 2571560, at *1 (same); *Hollington*, 2023 WL 4315747, at *4 (“To make his point, Hollington again relies on facts outside of the indictment to attack its sufficiency, which is impermissible.”).

Nor is Malik correct that “the Indictment appears to concede that [he] subjectively believed that his patients needed the ketamine and esketamine for their treatment-resistant depression.”¹⁰ (Drug Trafficking Mot., ECF No. 54, at 11.) At best, this position is outside the Indictment. At

⁹ The Government by no means concedes that the ketamine and Spravato treatments performed by Ali were for legitimate medical purposes. Nor does it concede that no patients were harmed as a result of these unsupervised treatments.

¹⁰ Equally unavailing is Malik’s assertion that “every single administration of ketamine and Spravato were [*sic*] done in Dr. Malik’s office where there was no chance of abuse.” (Drug Trafficking Mot., ECF No. 54, at 12.) This argument appears to be based on the unsubstantiated, nonsensical assumption that drugs cannot be abused so long as they are used in a medical suite.

worst, however, it contradicts the Indictment, which alleges Malik and Ali agreed that Malik “could simply ‘say hi’ to the ketamine patients, typically via telephone, as a purported justification for Dr. Ali handling their ketamine treatment” and that Malik and Ali agreed that “they would conceal that Dr. Ali was the actual rendering provider” of Spravato (and other) treatments by having Malik listed as the rendering provider on the medical notes and the claims to Medicare. (Indictment, [ECF No. 2](#), ¶¶ 43, 54-55.) In other words, the Indictment alleges (and the Government will prove at trial) that Malik acted in bad faith.

CONCLUSION

WHEREFORE, the United States respectfully asks the Court to **DENY** Mohd Azfar Malik, M.D.’s Motion to Dismiss the Drug Trafficking Counts ([ECF No. 54](#)) in its entirety.

Respectfully submitted,

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/s/ Amy E. Sestric

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CERTIFICATE OF SERVICE

I hereby certify that on March 28, 2024, the foregoing was filed electronically with the Clerk of the Court to be served by operation of the Court's electronic filing system upon all Counsel of Record.

/s/ Amy E. Sestric

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